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Document addresses improving quality, safety for PCIs performed without on-site backup

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The increasing number of percutaneous coronary interventions (PCIs) being performed at low-volume centers without on-site cardiac surgery backup has driven the need for new safety and quality protocols, according to an expert consensus document released today and written by a committee representing the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA). The document outlines steps hospitals can take to provide the safest possible environment for PCI when the facility does not provide cardiac surgery as a backup should complications occur.

"This issue was last reviewed in 2007, and since that time interventional cardiology has seen important changes," said Gregory J. Dehmer, MD, FACC, FSCAI, director of the Division of Cardiology at Baylor Scott & White Health, Central Texas (Temple, Texas) and the document's lead author. "The new recommendations aim to increase safety while maintaining access to quality care for underserved patients."

PCI is a common procedure performed to open blocked arteries. Frequently, a tiny metal mesh tube called a stent is used to help keep the artery open. There are two primary situations when a patient undergoes PCI: (1) during a heart attack, when emergency PCI is performed to open the completely blocked artery and limit damage to the heart muscle, and (2) during an elective procedure, a non-emergency situation

typically to relieve stable angina symptoms when medications alone are not completely effective.

Although PCI use increased significantly since the procedure was introduced more than 30 years ago, for a variety of reasons use peaked in 2006 and has since dropped by nearly a third. Advances in drug-eluting stents, greater use of medication to treat some types of blockages, increased emphasis on heart disease prevention, and new technologies to help physicians better evaluate blockages have all contributed to a drop in PCI use.

This drop has led to an increase in the number of facilities that are considered "low volume," or performing fewer than 200 PCIs per year, according to the consensus document. Overall, one-third of facilities performing PCI had no on-site cardiac surgery, and among those hospitals, about two-thirds were considered low volume.

The consensus document cites studies and meta-analyses since 2006 that find no indication of increased mortality or a greater need for emergency bypass surgery for either heart attack or elective PCI patients at sites without on-site cardiac surgery. In general, it said, safety questions about sites without surgical backup have diminished "in the presence of a proven, well-defined and protocol-driven approach."

However, the paper echoed an earlier joint recommendation that low-volume PCI programs "must have stringent systems and process protocols in place" with close monitoring of outcomes and strategies that encourage collaboration with higher-volume facilities.

"As the technique and equipment for PCI has improved, the evidence from randomized studies suggests that procedures can be performed safely without on-site surgery," said Dr. Dehmer. "But at the same time, the number of low-volume centers is increasing, making it essential that

those facilities without backup cardiac surgery have strict protocols in place to ensure the highest level of patient safety."

The consensus document compiles the recommendations made by various organizations in several different documents into one resource for use by facilities without on-site surgery. These include a greater emphasis on quality review programs, the recommended number of procedures physicians should perform per year to maintain their skills, mentoring for newly trained cardiologists and criteria to evaluate PCI programs. It also recommends a shift in focus to system-wide planning for rational distribution of PCI services.

"The expansion of small PCI programs without on-site surgery has not substantially improved access to PCI," said Dr. Dehmer. "Although the number of facilities capable of performing PCI has increased 44 percent, the number of people who live within a one-hour drive of a PCI facility has increased only slightly. Today about 80 percent of the population is within one-hour of a PCI hospital." Recent surveys found expansion of PCI reduced drive times for just 9 percent of the population.

The document also supports the ongoing study and surveillance of all PCI programs through participation in national databases, encourages public reporting of results and acknowledges further declines in PCI volumes might necessitate the closure of some PCI programs in the future.

The new consensus document, titled, "SCAI/ACCF/AHA Expert Consensus Document Update on Percutaneous Coronary Intervention without On-Site Surgical Backup," updates a 2007 consensus document. It will be published online today in *Catheterization & Cardiovascular Interventions*, *Journal of the American College of Cardiology* (*JACC*) and *Circulation: Journal of the American Heart Association*.